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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,465	09/05/2003	Norbert Moszner	20959/2130 (P 63013)	8449
7590 Nixon Peabody LLP Clinton Square P.O.Box 31051 Rochester, NY 14603-1051				
01/05/2010				
EXAMINER				
LEWIS, RALPH A				
ART UNIT		PAPER NUMBER		
3732				
MAIL DATE		DELIVERY MODE		
01/05/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/656,465

Applicant(s)

MOZSNER ET AL.

Examiner

Ralph A. Lewis

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 24 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 24 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 9/28/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Objection to New Matter Added to the Specification

The amendment filed 9/28/2009 adding new Figures 1-4 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention.

There is no support in the originally filed papers for the illustration in Figure 3 for the specifically illustrated film bag. The film bag is given length/width proportions not originally disclosed. There is no disclosure for the illustrated opening at one end. It is improper for applicant to add details and subject matter not originally disclosed after the application has been filed. Applicant is required to cancel the new matter in the reply to this Office Action.

Rejections based on 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is unclear how an inflatable bag is to be used as a carrier film for the disclosed resin film. The specification fails to reasonably disclose or teach how the inflatable bag is to be used with the disclosed polymer film.

In response to the present rejection applicant points to page 13, paragraph 4 as providing support for the claim. The examiner notes that the cited paragraph provides no reasonable basis for teaching one of ordinary skill in the art how to make and use the invention. There is no disclosure as to the shape or form of the bag, no disclosure as to how the bag is inflated, no disclosure as to what the bag is pushing against on the side opposite the carrier film, no disclosure as to how the "film bag" is formed etc. etc. etc.

Objections to the Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The specification provides no apparent basis for the "continuous polymer network" language in claim 1 or the "continuous addition polymer network" language of claim 27.

Rejections based on 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27, line 1, "file"?

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 17, 19 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimosawa et al (US 5,482,464).

Shimosawa et al disclose a dental resin sheet 1 for coating tooth surfaces which is formed of a flexible solid polymer film which is shaped around a tooth and then further polymerized with light to coat the surface of the tooth (column 4, lines 1-6). The Shimosawa et al dental resin sheet would inherently include a continuous polymer network.

In response to the present rejection, applicant argues that there is no disclosure that the Shimosawa et al dental resin sheet includes a "continuous polymer network" as required by the claims and that the resin material of Shimosawa et al may be of an uncured putty or dough-like material. The examiner is of the position that the "continuous polymer network" language is not set forth or defined in the written description, nor is it commonly used in the art (a text search of the US patent data base provides only a small handful of instances where the terminology is used); accordingly, it is reasonably subject to broad interpretation. In the present case, Shimosawa et al

discloses a network of polymer resin molecules that are held together in a continuous sheet. Moreover, applicant's remarks appear to indicate that the language requires at least some of the adjacent resin molecules to have bonded to one another; the examiner is of the position that such bonding of at least some of the adjacent resin molecules would inherently occur during or after manufacture even if the resin sheet had a putty like consistency – dental composites have a limited shelf-life due to the linking of adjacent resin molecules.

Additionally, Shimosawa et al do not indicate that the sheet is a paste, a liquid or dough, but rather a distinct sheet having distinct laminated layers which may be cut to the desired configuration of a tooth shape. The cut pieces maintain their shape when cut which reasonably would suggest to one of ordinary skill in the art that the sheet has at least some degree of partial polymerization.

Applicant's claims (nor remarks) give no guidance as to how much partial polymerization is necessary to meet the undefined "continuous polymer network" limitation; accordingly, the degree of polymerization necessary for meeting the broad limitation is minimal.

Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Kaelble (US 4,204,325).

Kaelble discloses a solid resilient continuous polymer film 12 (column 2, line 6-7 and 61-65) for coating tooth surfaces. The film may include methacrylate monomers that may be further cured by free radical reactions (column 3, lines 32-40).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8, 9, 11, 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimosawa et al (US 5,482,464) in view of Cornell (US 3,265,202).

Shimosawa et al fail to disclose the particular composition of the polymerizable film. Acrylates, methacrylates and polyurethanes are commonly used as dental materials as evidenced, for example, by Cornell who discloses a flexible dental polymer film comprising a non fiber-reinforced flexible film layer which comprises polymerizable groups capable of further polymerization, the film can be shaped around a tooth and cured by polymerization (column 1 line 16, column 1 line 37). To have merely selected common polymerizable dental materials for the dental material of Shimosawa et al as taught by Cornell would have been obvious to one of ordinary skill in the art. Moreover it is noted that Cornell further teaches at least a part of the polymerizable groups is radically polymerizable and a part of the polymerizable groups is cationically polymerizable. The film may include an initiator (column 9 line 50), organic fillers (column 9 line 17), polymerization inhibitors (column 7 line 34), pigments (column 9 line 72), and active substance (column 9 line 35). The film is detachably held on a carrier film, the carrier film being translucent, such that it can be polyethylene.

In regard to the "continuous polymer network" limitation, to the extent that the Shimosawa et al/Cornell polymer resin material does not meet the undefined limitation as explained above, then one of ordinary skill in the art would have found it obvious as a matter of routine practice to simply allow (or provide) the Shimosawa et al/Cornell resin sheet to partially cure as desired to a degree in which it has the consistency desired by the practitioner prior to being shaped over the tooth. More particularly, one of ordinary skill in the art would have found it obvious as matter of routine to provide the Shimosawa et al/Cornell resin sheets in a plurality of different flexibilities, stiffnesses, malleabilities by varying the degree to which adjacent resin molecules are linked.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shimosawa et al (US 5,482,464) in view of Cornell (US 3,265,202) as applied above and in further view of Mitra et al. (US 5,154,762).

Mitra et al teach a dental polymer comprising an initiator in microencapsulated form. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the film to have microencapsulated initiator in order to enhance shelf stability in view of Mitra et al.

Claims 10, 12, 13, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimosawa et al (US 5,482,464) in view of Cornell (US 3,265,202) as applied above and in further view of Prasad et al. (US 6,039,569).

Prasad et al. teach a dental film having an antioxidant (column 3 line 49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the film to have a known additive such as an antioxidant in the film for enhanced antioxidant properties. Prasad et al. teach the film having the side facing the tooth surface coated with a primer. It would have been obvious to one of ordinary skill in the art to have a coating of primer to promote adhesion of the film to the tooth surface. Prasad et al. teach a dental film and adhesive. It would have been obvious to include adhesive to the tooth surface to improve wetting and adhesion of the film to the surface.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimosawa et al (US 5,482,464) in view of Cornell (US 3,265,202) as applied above and in further view of Vallittu et al. (US 6,197,410).

Vallittu et al. teach a dental film with polymeric material coating which is not adhesive in quality on the side facing away from the tooth surface. It would have been obvious to one of ordinary skill in the art at the time the invention was made to call the polymeric material of an anti-adhesive additive and to have such a coating to improve cosmetic qualities in view of Vallittu et al.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shimosawa et al (US 5,482,464) in view of Cornell (US 3,265,202) as applied above and in further view of Karazivan (WO 01/93774).

Karazivan teaches the film detachably held on a carrier film in the form of an inflatable film bag (page 12, line 27). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the film of Shimosawa et al having the carrier film of Karazivan in order to better adapt the dental film to the applied surface.

Action Made Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (571) 273-8300. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Cris Rodriguez, can be reached at (571) 272-4964.

R.Lewis
January 4, 2010

/Ralph A. Lewis/
Primary Examiner, Art Unit 3732